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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,281	07/06/2000	Clive M. Elson	CGR-013CP2	5564

959 7590 10/20/2003

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/610,281</b>	Applicant(s) <b>Elson et al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

### Status

- ☒ Responsive to communication(s) filed on **-07/14/03 (IDS#2), 07/22/03 (amdt B) & 10/15/03 (Terminal Disclaimer)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claims **---1-5 and 8-17---** are pending in the application. Claims **-6, 7 and 18-26-** have been cancelled. Of the above claim(s) **---[]---** is/are withdrawn from consideration.
- ☐ Claim(s) **---[]---** is/are allowed.
- ☒ Claims **---1-5 and 8-17---** are rejected.
- ☐ Claim(s) **---[]---** is/are objected to.
- ☐ Claim(s) **---[]---** are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-[]-** is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-[]-**.

### Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--07--**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**

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Claims 6, 7 and 18-26 have been cancelled, no claim has been amended, and no new claims have been added as per the amendment filed July 22, 2003. A supplemental Information Disclosure Statement (IDS) filed July 14, 2003 has been received with all cited references and made of record. A Terminal Disclaimer received on July 22, 2003 and re-filed by FAX in corrected form on October 15, 2003 has been found acceptable in its amended form and made of record.

Claims 1-5 and 8-17 remain in the case.

Incorporation by reference of essential material by reference to a foreign application or a foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by applicant, or a practitioner representing applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCAP 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to any other reference including US patents is improper because applicant has not provided the proper direction concerning which particular part or parts thereof is/are to be incorporated and provided the appropriate declaration therewith. See the disclosure at page 4-5, bridging sentence; and page 6, at lines 18-19. Deletion of all such incorporations by reference is respectfully requested.

Applicant's arguments filed July 22, 2003 have been fully considered but they are not deemed to be persuasive.

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Applicant argues that the noted incorporations by reference are of non-essential subject matter. In light of the location of the incorporations, examiner respectfully disagrees, noting that the rule does not apply to discussion of the prior art and therefore that applicant  
5 may elect to move the noted incorporations into that portion of the disclosure. Otherwise, the above stated objection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

10 "A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

20 (e) the invention was described in a patent granted on an application to another filed in the United States before the invention thereof by applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Claims **1-5 and 8-17** are rejected under 35 U.S.C. §102(e) as being anticipated by **MacPhee et al. '325** (PTO-892 ref. D).

25 **MacPhee et al. '325** at claim **18** discloses the utility of N, O-dicarboxymethyl-chitosans (NOCC) based compositions in the introduction of medicinal compounds to moist tissue to permit the sustained release of the medicinal compound into said tissue.

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Claims **1-5 and 8-17** are rejected under 35 U.S.C. §102(b) as being anticipated by **Elson '988** (PTO-892 ref. **G**).

5 **Elson '988** at column 6, at lines 50-64 and specifically at lines 60-61, discloses covalent linking of NOCC with a variety of different pharmaceutical substances to permit administration of the NOCC derivatives formed thereby as a gel to provide sustained *in vivo* release of the linked substance, the administration of which to treat medicinal conditions is provided for by claim **30**.

10 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 is **(703) 308-4556**.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **703-308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

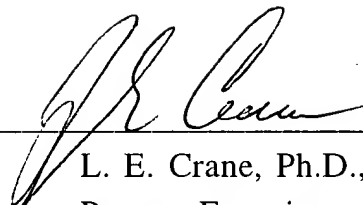
Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **703-308-1235**.

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LECrane:lec  
10/19/03

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600

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